

REMARKS

With the foregoing amendment, Applicant, in effect, has replaced the original claims 1-97 with new claims 98-164. It is believed that these claims are patentable over the prior art. Entry of this Preliminary Amendment and action toward a Notice of Allowance is solicited.

Respectfully submitted,



Michael D. Beck
Reg. No. 32,722
Maginot, Moore & Bowman
111 Monument Circle, Suite 3000
Indianapolis, IN 46204
(317) 638-2922 (phone)
(317) 638-2139 (fax)
mdbeck@maginot.com

Clean Version of the Amendment to the Specification

Prior to the first line of the specification and after the title, please enter the following:

Reference to Related Application

This application is a continuation of co-pending U.S. Application No. 09/872,905, filed on June 1, 2001, entitled "Tissue Distraction Device" in the name of the same inventors, which claims priority to U.S. Provisional Application No. 60/274,372, filed on March 8, 2001.

Clean Version of the New Claims

Please add the following as new claims 98-164:

98. A method for distracting in a given direction two tissue surfaces comprising consecutively introducing a plurality of elements in contact with each other between the tissue surfaces to distract such tissue surfaces generally in the given direction as elements are consecutively introduced.
99. The method of claim 98 wherein said elements are introduced by moving at least one element to a different position upon introduction of a subsequent element.
100. The method of claim 99 wherein said at least one element is moved by contacting a surface thereof with a surface of said subsequent element.
101. The method of claim 100 wherein the introducing step includes the step of placing an elongated access channel in communication with a space between said tissue surfaces and introducing the elements through said channel.
102. The method of claim 101, further including the step of providing a bone filler in contact with the elements.
103. The method of claim 100 wherein said elements are wafers, said wafers being introduced between said tissue surfaces by stacking one wafer atop another wafer.
104. The method of claim 98, wherein said elements are introduced by sliding one element along a surface of another element.
105. The method of claim 98, further including the step of providing an outer member and introducing said elements into said member.
106. The method of claim 98, wherein said elements have arcuate contact surfaces.
107. The method of claim 98, wherein said elements have generally flat contact surfaces.

108. The method of claim 98, wherein said tissue surfaces are superior and inferior surfaces of a damaged or diseased vertebral body in a spine, and wherein the elements are consecutively inserted into the vertebral body to distract said superior and inferior surfaces until the normal height of the vertebral body is substantially attained.
109. The method of claim 98, wherein said tissue surfaces are superior and inferior endplate surfaces of opposing vertebral bodies in a spine, and wherein the elements are consecutively inserted between said vertebral bodies to distract said opposing superior and inferior endplate surfaces until stability of the vertebral bodies is substantially achieved.
110. The method of claim 98, wherein said tissue surfaces are surfaces of a damaged or fractured tibia, and wherein the elements are consecutively inserted between the surfaces to distract such surfaces until the damage or fracture is substantially reduced.
111. A method for supporting in a given direction two tissue surfaces comprising consecutively introducing between the tissue surfaces a plurality of elements in contact with each other generally in the given direction until said tissue surfaces are supported.
112. The method of claim 111, wherein said elements are wafers configured for stacking one atop another.
113. The method of claim 111, wherein said elements are introduced by moving at least one element to a different position in the given direction upon introduction of a subsequent element.
114. The method of claim 113, wherein said elements are introduced by sliding one element along a surface of another element.
115. The method of claim 111, further comprising the step of introducing a bone filler in contact with said plurality of elements.

116. The method of claim 111, wherein said elements are introduced in a manner to simultaneously distract and support said tissue surfaces.
117. An apparatus for the support of tissue surfaces in a given direction, comprising a plurality of elements in cooperative contact forming a structure between said tissue surfaces generally extending in the given direction, said elements being configured for consecutive receipt between said tissue surfaces to thereby form said structure as said elements are received.
118. The apparatus of claim 117, wherein each element has an interface, the interfaces of elements in contact being configured to provide said cooperative contact.
119. The apparatus of claim 118, wherein said interfaces are configured to provide unconstrained degrees of cooperative contact.
120. The apparatus of claim 118, wherein said interfaces are configured to provide semi-constrained selective degrees of cooperative contact.
121. The apparatus of claim 118, wherein said interfaces are configured to provide constrained degrees of cooperative contact.
122. The apparatus of claim 118, wherein said interfaces are arcuate.
123. The apparatus of claim 122, wherein said arcuate surfaces are generally cylindrical.
124. The apparatus of claim 122, wherein said arcuate surfaces are generally spherical.
125. The apparatus of claim 118, wherein said interfaces are generally flat.
126. The apparatus of claim 125, wherein said structure is defined by a plurality of wafers each having said generally flat interfaces, one wafer being disposed atop another wafer to form said structure.

127. The apparatus of claim 117, wherein said tissue surfaces are superior and inferior surfaces of a damaged or diseased vertebral body in a spine, and wherein said elements are configured for consecutive receipt into said vertebral body to form said structure between said superior and inferior surfaces of said vertebral body.
128. The apparatus of claim 117, wherein said tissue surfaces are superior and inferior endplate surfaces of opposing vertebral bodies in a spine, and wherein said elements are configured for consecutive receipt between said vertebral bodies to form said structure between said superior and inferior endplate surfaces of said opposing vertebral bodies.
129. The apparatus of claim 117, wherein said tissue surfaces are surfaces of a damaged or fractured tibia, and wherein said elements are configured for consecutive receipt between said surfaces to form said column between such surfaces.
130. An apparatus for the distraction and support of tissue surfaces in a given direction, comprising a plurality of stackable wafers cooperatively forming a column generally in the given direction between said tissue surfaces, the wafers each having a contact surface, a contact surface of one wafer being slidably receivable on a contact surface of another wafer in a sliding direction generally normal to the given direction.
131. The apparatus according to claim 130, wherein a stackable wafer comprises a single wafer.
132. The apparatus according to claim 130, wherein a stackable wafer comprises multiple wafers.
133. The apparatus of claim 130, wherein one or more wafers are curved in a plane generally normal to the direction of the axis of the column.
134. The apparatus of claim 130, wherein one or more wafers are of non-uniform thickness.

135. The apparatus of claim 130, wherein each wafer has a length and a width and wherein one or more wafers increases in thickness along the wafer length such that the one or more wafers are configured as a wedge.
136. The apparatus of claim 130, wherein the wafer contact surfaces are provided with complementary configurations to restrain the wafers from slipping out of the column.
137. The apparatus of claim 136, wherein the complementary configurations are complementary ridges and grooves.
138. The apparatus of claim 137, wherein the complementary ridges and grooves have dovetail ridge and groove configurations.
139. The apparatus of claim 136, wherein the complementary configurations are configured to enable the wafers to rotate in a plane normal to the given direction while remaining in the column.
140. The apparatus of claim 136, wherein the complementary configurations comprise detent configurations so configured as to restrain any lateral movement between adjacent wafers in a column.
141. The apparatus of claim 136, wherein the complementary configurations comprise a cylindrical indent.
142. The apparatus of claim 136, wherein the complementary configurations comprise a spherical indent.
143. The apparatus of claim 136, wherein the wafer contact surfaces are configured to permit limited rotation of one wafer with respect to another wafer about an axis parallel to the sliding direction.
144. The apparatus of claim 130, wherein the wafers comprise a dovetail and a cylindrical indent to constrain all degrees of freedom.

145. The apparatus of claim 130, wherein the wafer contact surfaces have cylindrical interfaces to provide axial translation along the axis of the cylinder and rotational movement about the radius of the cylinder.
146. The apparatus of claim 130, wherein the wafers have spherical interfaces.
147. The apparatus of claim 130, further including a pin for locking the wafers in place.
148. The apparatus of claim 130, wherein each wafer has a leading edge, a trailing edge, and two lateral edges, the wafer further including a lip formed along a bottom surface for limiting axial travel of a subsequent wafer.
149. The apparatus of claim 148, wherein the lip extends along all edges of the bottom surface except for the trailing edge.
150. The apparatus of claim 148, wherein the lip extends along the leading edge of the bottom surface.
151. The apparatus of claim 148, wherein the lip extends along the lateral edges of the bottom surface.
152. The apparatus of claim 130, wherein the wafers are marked with a radio-opaque material for observation under fluoroscopy.
153. The apparatus of claim 130 wherein each wafer has a length and a width and wherein the wafer defining the bottom wafer in said column has a length larger than at least one other wafer in said column.
154. The apparatus of claim 130 wherein each wafer has a length and a width and wherein the wafer defining the top wafer in said column has a length larger than at least one other wafer in said column.

155. The apparatus of claim 154 wherein said wafer defining said bottom wafer in said column has a length larger than at least one other wafer in said column.
156. The apparatus of claim 130 wherein said wafers comprise implant materials.
157. The apparatus of claim 156, wherein one or more wafers have at least one orifice for receiving a filler material therein.
158. The apparatus of claim 157, wherein said wafers further comprise osteoinductive agents.
159. The apparatus of claim 158, wherein said wafers further comprise a drug therapy.
160. The apparatus of claim 130 further including an outer member covering at least a portion of such wafer column.
161. The apparatus of claim 160, wherein said outer member is permeable.
162. The apparatus of claim 161, wherein said permeable outer member comprises a material of macro-porosity.
163. A kit for use in the distraction of tissue surfaces in a given direction, comprising;
 - a plurality of elements adapted for contact with each other; and
 - an inserter for consecutively inserting a plurality of elements between said tissue surfaces in a manner such that such elements are placed in contact with each other in a direction generally extending in the given direction.
164. The kit of claim 163 further including bone filler.